IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JESSE PEETZ, Plaintiff, vs. GENENTECH, INC., a California corporation, et al., Defendants.	8:10-CV-297 MEMORANDUM AND ORDER

This matter is before the Court on the Plaintiff's Statement of Objections to Magistrate Judge's Order (filing 113). The Court finds merit to the plaintiff's objection and will modify the Magistrate Judge's order.

BACKGROUND

The plaintiff's complaint alleges several claims for relief arising out of the use of the drug Rituxan to treat the plaintiff's thrombotic thrombocytopenic purpura (TTP). Filing 1. TTP is an autoimmune disorder, and Rituxan is an immunosuppressant. Filing 1 at 3. Defendants Genentech and Biogen promote Rituxan, and Genentech manufactures it. Filing 20 at 1; filing 30 at 1. Rituxan is FDA-approved for treating lymphoma, but the record suggests that Rituxan has been used "off-label" to treat other conditions, particularly autoimmune diseases such as rheumatoid arthritis, systemic lupus erythematosus, and TTP. *See*, filing 105-3; filing 105-4; filing 105-5; filing 114-2; filing 114-3.[1] The plaintiff alleges that the defendants marketed Rituxan as a safe and effective treatment for TTP, but that when Rituxan is administered over time, there is a risk of serious injury and death resulting from a compromised immune system. Filing 1 at 3-4. That risk, the plaintiff claims, resulted in the plaintiff suffering a viral infection that

[1] Genentech argues that the Court should strike the exhibits presented in support of the plaintiff's objection, because under NECivR 72.2(b)(1), in objecting to a Magistrate Judge's nondispositive order, "[a] party may not offer additional evidentiary materials without a court order." Filing 115 at 5-6. The Court declines to do so, for two reasons. First, while the Court has referred to some of that evidence for background information to establish context, the Court does not find it to be legally dispositive. Second, the Court has little difficulty in construing the plaintiff's submission of an index of evidence as implicitly seeking leave to submit it, and the Court grants such leave.

ultimately paralyzed him. Filing 1 at 4-5. But, the plaintiff alleges, "[t]he risks that ultimately befell [the plaintiff] were not unique to the 'off-label' use of Rituxan"; instead, those risks "would affect any user of Rituxan regardless of whether the use was federally approved." Filing 1 at 3.

The plaintiff served a number of deposition notices pursuant to Fed. R. Civ. P. 30(b). As relevant, three of the notices required the defendant to designate 30(b) witnesses knowledgeable in "all methods of marketing of Rituxan[,]" the defendants' "use of medical science advisors for Rituxan[,]", and the defendants' "compensation to physicians for writing, speaking, preparing posters or otherwise recommending the use of Rituxan." Filing 93 at 1; filing 94 at 1; filing 95 at 1. Genentech filed a motion for a protective order with respect to those three notices. Filing 101.

Genentech's argument, generally stated, was that its promotional efforts in support of Rituxan were irrelevant, because the plaintiff's treating physician said she had not been exposed to that marketing before prescribing Rituxan to the plaintiff. *See* filing 101 at 2. So, Genentech reasoned, there was no link between Genentech's promotion of Rituxan and the plaintiff's use of the product. Filing 101 at 2. And, Genentech argued, requiring it to produce a witness to testify to such matters would be unduly burdensome. Filing 101 at 2.

The plaintiff contended, however, that the plaintiff's physician had been influenced by medical literature, and had consulted with other physicians who had themselves been influenced by medical literature and conference presentations. Filing 104 at 4-10. So, the plaintiff argued, discovery was required to explore whether Genentech had marketed Rituxan by influencing those authors and other prominent medical professionals—and thus, indirectly, influenced the physicians who participated in the decision to prescribe Rituxan to the plaintiff. Filing 104 at 13.

The Magistrate Judge, for the most part, agreed with the plaintiff. Filing 112. The Magistrate Judge rejected Genentech's contention that the requested discovery would be unduly burdensome, noting that Genentech had presented no evidence of the time or expense that would be necessary to prepare or present a 30(b) witness on the disputed topics. Filing 112 at 3. And, the Magistrate Judge found, the plaintiff had demonstrated that exploring the disputed topics might lead to admissible evidence regarding the use of Rituxan to treat the plaintiff's TTP. Filing 112 at 4. But, the Magistrate Judge decided,

> The plaintiff has not shown how Genentech's general marketing practices, general use of medical science advisors, or general compensation of physicians regarding Rituxan—unrelated to its

> use of treating TTP—are in any way relevant to his claims. To the extent Plaintiff seeks information on the disputed 30(b)(6) topics beyond the off-label use of Rituxan to treat TTP, Genentech's motion for a protective order is granted.

Filing 112 at 4. So, the Magistrate Judge ordered that "each of the three contested Rule 30(b)(6) topics at issue in Genentech's motion is limited in scope to the use of Rituxan to treat TTP." Filing 112 at 5. The plaintiff objects to the Magistrate Judge's order.

ANALYSIS

The plaintiff contends that the Magistrate Judge's ruling was in error because the risk of infection alleged by the plaintiff is not unique to the use of Rituxan to treat TTP. Filing 113 at 3. The plaintiff alleges that "any patient who takes Rituxan over the long term shares that risk of exposure, whether he takes Rituxan for TTP or rheumatoid arthritis or lupus." Filing 113 at 3. The plaintiff's theory of the case is, generally stated, that Genentech knew long-term use of Rituxan carried a risk of severe immunosuppression, but nonetheless promoted Rituxan as a safe and effective off-label treatment for a variety of medical conditions, without warning users of the associated risk. *See* filing 113 at 3-4. In other words, the plaintiff claims that Rituxan is dangerous regardless of what condition it is being used to treat.[2]

Given that theory of the case, the Court agrees with the plaintiff that discovery into Genentech's marketing efforts, beyond the use of Rituxan to treat TTP, may produce relevant evidence. Suppose, for instance, that Genentech promoted Rituxan as a safe and effective treatment for rheumatoid arthritis. That would advance two distinct factual claims: (1) Rituxan is safe, and (2) Rituxan is an effective treatment for rheumatoid arthritis. Whether Rituxan can effectively treat the symptoms of conditions other than TTP is, the Court agrees, unlikely to produce evidence relevant to the plaintiff's claims. But to the extent that Genentech's promotional efforts may have conveyed the idea that Rituxan was safe for long-term use,[3] they

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[2] This is not to say that the condition a drug is used to treat is irrelevant in determining whether its manufacturer may be liable for any resulting injuries. For instance, under Nebraska law, a drug manufacturer may defend against a design defect claim by showing, among other things, that the benefits of a drug justify its risks. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000). Such an analysis balances the danger of taking a drug with the threat posed by the underlying medical condition. *See id.* at 839.

[3] That idea could be conveyed through commission or omission. If the long-term use of Rituxan was known by Genentech to be dangerous, then *any* promotion that failed to explain that risk might be seen as a missed opportunity to warn potential users. An article

might prove relevant to the plaintiff's claim that Genentech concealed a risk of immunosuppression.

A district court may reconsider a magistrate judge's ruling on nondispositive pretrial matters only where it has been shown that the ruling is clearly erroneous or contrary to law. *See,* 28 U.S.C. § 636(b)(1)(A); *Ferguson v. United States*, 484 F.3d 1068 (8th Cir. 2007). Here, the Court finds that the Magistrate Judge erred in her construction of the plaintiff's claims.[4] That error was understandable—in the proceedings before the Magistrate Judge, the parties were focused on the literature discussing whether Rituxan was an effective treatment for TTP, and did not extensively discuss the relevance of marketing the drug for other off-label uses. Nonetheless, such marketing is at least potentially encompassed by the plaintiff's claims, to the extent that it presented or omitted information about the safety of the drug. The Court will sustain the plaintiff's objection, and modify the Magistrate Judge's order to reflect the Court's broader understanding of the plaintiff's claims.

Genentech argues, in passing, that the Magistrate Judge's "limitation of the noticed topics to the use of Rituxan to treat TTP is necessary to avoid irrelevant and burdensome discovery." Filing 115 at 7. To the extent Genentech is again asserting that the plaintiff's discovery requests are unduly burdensome, the Court finds no merit to that argument. It was rejected by the Magistrate Judge, filing 112 at 3, and Genentech has not objected. And the Court notes, as did the Magistrate Judge, that Genentech has made no showing in support of its assertion of an undue burden. *See Gen. Dynamics Corp. v. Selb Mfg. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973) (burden on party resisting discovery to make particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statement).

IT IS ORDERED:

1. The Plaintiff's Statement of Objections to Magistrate Judge's Order (filing 113) is sustained.

2. The Magistrate Judge's Memorandum and Order (filing 112) is modified such that each of the three contested Rule

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that said, "Rituxan controls the symptoms of arthritis, but oh, by the way, it might kill you" would seem unlikely to escape the attention of a physician researching the drug, even if the physician was interested in treating a different condition.

[4] The Court sees this as more an error of law than of fact, as it essentially involves construction of the plaintiff's claims, and the interpretation of a pleading is a determination of law. *Hammonds v. Hartford Fire Ins. Co.*, 501 F.3d 991, 998 (8th Cir. 2007). But the Court would reach the same result regardless of which standard of review is applied.

30(b)(6) topics at issue in Genentech's motion for protective order is limited in scope to the use of Rituxan to treat TTP *or* the safety or risks of using Rituxan, including the failure to warn of any such risks.

Dated this 5th day of September, 2013.

BY THE COURT:

John M. Gerrard
United States District Judge